VIRGINIA MOLNUPIRAVIR EMERGENCY USE CHECKLIST

Last Updated: 1.25.22

This form is to be completed by the prescribing provider to assist in determining patient eligibility for molnupiravir. This checklist is based on currently available evidence, resources, information, emergency use authorization (EUA) and expert opinion and is subject to change.

Prescribing Provider Name: _____ Date and time of prescription: _____
Patient name: _____ Patient Date of Birth: _____

REQUIRED TESTING PRIOR TO ADMINISTRATION

- COVID-19 RT-PCR or antigen test
- Vital Signs, including weight in kilograms (kg), and Pulse Oximetry

INCLUSION CRITERIA

All must be included to be compliant with EUA

- COVID-19 Positive via PCR or antigen, positive test date: _____
- Patient is 18 years of age or older
- High risk for progression to severe COVID-19, including hospitalization or death
- Alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate
- Time since symptom onset, **less than 5 days**. Approximate **symptom onset date**: _____
    - Please circle symptoms that apply:
        - Cough
        - Shortness of breath or difficulty breathing
        - Fever
        - Chills
        - Muscle pain
        - Sore throat
        - GI symptoms
        - Diarrhea
        - Other_____
- Does patient have mild to moderate COVID-19 disease? Yes / No

EXCLUSION CRITERIA

Any below are contrary to authorized use.

- Patient is less than 18 years of age
- Known hypersensitivity to any ingredient of molnupiravir
- Initiation of treatment in a patient hospitalized due to COVID-19
- For use as pre-exposure or post-exposure prophylaxis for prevention of COVID-19
- For use after patient has had symptoms for 5 days

MOLNUPIRAVIR DOSING AND COUNSELING

- 800 mg (four 200 mg capsules) taken orally every 12 hours for 5 days, with or without food
- Completion of the full 5-day treatment course and continued isolation in accordance with public health recommendations are important to maximize viral clearance and minimize transmission of SARS-CoV-2
- No adjustment needed for renal or hepatic impairment or in geriatric patients
- Females of childbearing potential should use a reliable method of contraception correctly and consistently, as applicable, for the duration of treatment and for 4 days after the last dose of molnupiravir
- The prescribing healthcare provider must assess whether a female of childbearing potential is pregnant or not, if clinically indicated
- Males of reproductive potential who are sexually active with others of childbearing potential should use a reliable method of contraception correctly and consistently during treatment and for at least 3 months after the last dose
- Note: Not authorized for use for longer than 5 consecutive days

It **MUST be documented in the patient's medical record prior to prescribing** of molnupiravir that **informed consent** process took place, in which the risks, benefits, unknowns of the proposed treatment, and reasonable treatment alternatives were discussed with patient/surrogate and their acceptance or refusal documented and the **patient/surrogate has been provided the following**:

- The Fact Sheet for Patients and Parents/Caregivers: https://www.fda.gov/media/155055/download
- Informed of alternatives to receiving molnupiravir
- Informed that molnupiravir is an unapproved drug that is authorized for use under EUA

If a serious and unexpected adverse event occurs and appears to be associated with the use of molnupiravir, the prescribing health care provider and/or the provider's designee shall complete and submit a MedWatch form within 7 calendar days from the onset of the event to the FDA using one of the following methods:

- Complete and submit the report online: https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting, or
- Use a postage-paid Form FDA 3500 (available at http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM163919.pdf) and return by mail (MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787), or by fax (1-800-FDA-0178), or
- Call 1-800-FDA-1088 to request a reporting form

CONDITIONS OF AUTHORIZATION FOR THE USE OF MOLNUPIRAVIR FROM THE STATE OF VIRGINIA.

- You attest that all information in this form is true to the best of your ability
- You may contact the pharmacy to verify they have supply and send them the copy of the COVID-19 positive test result
- You agree to complete and submit a MedWatch form for all adverse reactions and serious adverse or unexpected adverse events that are considered potentially attributable to molnupiravir as directed by the EUA issued by the FDA for molnupiravir within 7 calendar days from the onset of event (refer to EUA for reportable events)

- You may submit all serious adverse events and all medication errors to the State of VA by reporting the event(s) to the Virginia Poison Center at (800) 222-1222 as soon as possible but no later than three days after time of error or adverse reaction